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    IN THE UNITED STATES DISTRICT COURT FOR THE
            NORTHERN DISTRICT OF OKLAHOMA
 2
                            )MDL DOCKET NO. 16-MD-2700
 3
    IN RE:
                            )ALL CASES
 4
    GENENTECH HERCEPTIN
                            )Proceeding: Initial Case
    (TRASTUZUMAB) MARKETING ) Management Conference
 5
    AND SALES PRACTICES
                            )Date: 6-23-16
                            )Court Time: 10:00 a.m.
    LITIGATION
 6
                            )
 7
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                  TRANSCRIPT OF HEARING
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11
           Before the Honorable Terence K. Kern
12
                   June 23, 2016.
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21
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23
            ELIZABETH ANN BEHLES, CSR #121
24
25
        -MIDWEST REPORTING, INC. 918.455.2631 -
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2					
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20	And MR. WILLIAM W. O'CONNOR Attorney at Law				
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23					
24					
25					
l	MIDWEST REPORTING, INC. 918.455.2631				

1 2 This matter comes on THE COURT: 3 for case management conference In Re: 4 Genentech Herceptin, MDL docket's 16-2700 on 5 I'm glad to see that so many of you 00:00 6 were able to make it. You're traveling in 7 packs for safety reasons? 8 All right. We've got a number of 9 things to handle and this is our first 10 meeting in this MDL case, and we'll try to 00:00 11 establish as much as we can. 12 I think initially I need to get appearances for the Record, so if we could 13 14 start with the plaintiffs, please. 15 MR. KEGLOVITS: Your Honor, Dave 00:00 Keglovits on behalf of -- there are 15 cases 16 17 and we represent 14 plaintiffs in 14 of those 18 cases. I'm happy to go through each of those 19 for your Honor if you want to hear each of those, but I just want to advise you that 20 00:01 21 that's the allocation. Mr. Sill, Sill Law 22 Group represents the plaintiff in the other 23 case, the Comanche County Memorial Hospital 24 case. 25 Okay. THE COURT: 00:01

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1
                     MR. ADAMS: Steve Adams
       2
          representing the plaintiffs, co-counsel with
       3
          Mr. Keglovits.
                     MR. DOVERSPIKE: Adam Doverspike
       4
       5
          also representing the same co-counsel with Mr.
00:01
       6
          Keglovits.
       7
                     MR. SILL: Your Honor, James Sill
       8
          representing Comanche County Memorial
          Hospital, and as indicated we are in the
       9
      10
          submission presented in court, as I'm sure his
      11
          Honor has seen, asking that David be appointed
      12
          as lead counsel, and that we be appointed as
      13
          co-lead, so consequently I'll only be speaking
      14
          when asked this morning.
      15
                     THE COURT: All right.
00:01
      16
                     MR. BERGIN: Christopher Bergin,
      17
          also from the Sill Law Group on behalf of the
      18
          Comanche County Memorial Hospital.
      19
                     MS. TABATABAIER: Tara Tabatabaier
          also from the Sill Law Group on behalf of
      20
00:01
          Comanche County Memorial Hospital as well.
      21
      22
                     THE COURT: All right.
                                              Is that all
      23
          from the plaintiffs' side?
      24
                     MR. KEGLOVITS: Your Honor, Bill
      25
          O'Connor on behalf of Genentech, and with me
00:02
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1
          is Alicia Donahue and Jim Muehlberger.
       2
                     MR. MUEHLBERGER:
                                        Good morning,
       3
          your Honor.
                     MS. DONAHUE: Good morning, your
       4
       5
          Honor.
00:02
       6
                     THE COURT: Good morning.
                                                There
       7
          have been some late filings. We used to call
       8
          that years ago, fillings that came over the
       9
          transom. And you younger lawyers will not
      10
          understand that terminology at all; it's a
00:02
          ventilation system in old buildings. You
      11
      12
          could just throw it over the top of -- the
      13
          windows on top of the doors. And we'll get to
      14
          those as they come up.
                     Okay. Mr. Keglovits, you indicated
      15
00:03
      16
          there are 15 cases now; you represent 14?
      17
                     MR. KEGLOVITS: Your Honor, through
      18
          this week there are actually 16 plaintiffs.
      19
          We represent 15 of the plaintiffs. I believe
      20
          there are 13 or 14 cases.
00:03
      21
                     One of the cases is relatively new
          and thus has not been tagged with a
      22
      23
          conditional transfer order, so it might not be
          on what the Court has. It's -- the style is
      24
      25
          Blue Ridge Cancer Center in Virginia as the
00:03
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1 plaintiff. The others I believe all have 2 either been transferred to your Honor, or in 3 the case of Shindell Oncology case, a conditional transfer order has been provided 4 5 and should be --00:03 THE COURT: Okay, and so there are 6 7 some that we're unaware of. Let's talk about that while we have this opportunity. 8 9 What do you anticipate; what do you have knowledge of? Are there other cases that 10 00:04 you believe are going to be included, or are 11 12 there other cases that are -- will be filed? 13 MR. KEGLOVITS: There are other 14 practice groups who are interested in participating, I think -- I don't want to get 15 00:04 16 too deep into the issues, but from our 17 perspective if we were permitted to file the 18 Third Amended Complaint that we've asked the 19 Court to allow us to file, which would include a national class allegation, that would make 20 00:04 21 it unnecessary for us to continue to stand up using individualized actions in other 22 23 jurisdictions. We're not aware of any other firms that are interested in bringing the 24 25 case, at least at this point. 00:04

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THE COURT: And if, in fact, a
       1
       2
          class action were allowed, what kind of
       3
          numbers do you think you're looking at?
                     MR. KEGLOVITS: In terms of the
       4
       5
          number of class members?
00:04
       6
                     THE COURT: Yes.
       7
                     MR. KEGLOVITS: In the thousands.
                     THE COURT: Okay. So Herceptin was
       8
          basically sold to and used by facilities
       9
      10
          throughout the United States, and those
00:05
          facilities would number certainly in the many
      11
      12
          hundreds, if not thousands.
      13
                     MR. KEGLOVITS: Yes, your Honor.
          It's also sold outside of the United States,
      14
      15
          but as the proposed classes have been defined,
00:05
      16
          at least at this point, those groups would not
      17
          be included in this case.
      18
                     THE COURT: All right. One of the
      19
          matters that has been discussed that we need
          to determine is of service of additional
      20
00:05
      21
                   There was an indication that the
          cases.
      22
          plaintiff wanted to serve by email and that
      23
          was objected to, and I think appropriately.
                     Mr. O'Connor, is there objection to
      24
      25
          service by a certified mail, return receipt?
00:06
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1 MR. O'CONNOR: Your Honor, one of 2 the issues was we have some foreign entities 3 that have not been served. We don't represent 4 them, and that -- and in addition to that, 5 there was a concern on our side that any kind 00:06 6 of email would be a potential waiver of 7 jurisdiction, venue and other issues. So we 8 had, prior to all of these additional suits coming in, and certainly long before we 9 10 received the proposed Third Amended Complaint, 00:06 11 we had talked about a stipulation that 12 basically resolved any concerns we had on the 13 defense. 14 So one thing we could certainly do is go back and try to reach this same 15 00:07 16 stipulation or a similar one that would 17 resolve some of the issues, not certainly with 18 respect to the foreign entities, but would set 19 forth a -- that it's not a waiver of defenses; that we were not agreeing to any kind of 20 00:07 21 service by certified mail or otherwise of any parent or subsidiary or any division of 22 23 Genentech. So we had kind of anticipated this 24 when we first were preparing the proposed CMO. 25 And I would ask your Honor if we could have 00:07

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1
          some time to maybe try to reach a similar
       2
          stipulation that would outline the absence of
       3
          any waiver on our part. We'd limit who, if it
          was service by certified mail, who that could
       4
       5
          be on, and still preserve the need for them
00:07
          to, you know, comply with the Hague convention
       6
       7
          and whatever else they'd do if they intended
          to pursue these foreign companies.
       8
       9
                     THE COURT: You want to have
          certified mail just to you and then you take a
      10
00:08
      11
          vacation? All right. Have the foreign
      12
          entities been served?
      13
                     MR. O'CONNOR: Not to our knowledge.
      14
          There was --
      15
                     THE COURT: There was some
00:08
          indication --
      16
      17
                     MR. O'CONNOR:
                                     They --
      18
                     THE COURT: -- of service in the
      19
          first few cases was considered appropriate.
      20
                     There was service on Genentech, and
80:00
          there was certainly service on the United
      21
      22
          States Roche Holdings, but not on anybody
      23
          else. And, frankly, as service has proceeded
      24
          there hasn't been a whole -- any problems to
      25
          our knowledge, so I don't understand why there
00:08
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1
          would have to be some novel service issue
       2
                  They've, they've accomplished it, and
          anyway.
       3
          to date -- well, I don't think certified mail
          is novel though. We've had that for a while.
       4
       5
                     MR. O'CONNOR: Sure, yeah. We had
00:09
       6
          had this stipulation in mind to try to --
       7
          which we were on the eve of presenting to your
       8
          Honor when more cases came along and new
          counsel came in.
       9
      10
                     THE COURT: Mr. Keglovits, do you
00:09
      11
          care about the foreign entities?
      12
                     MR. KEGLOVITS: Well, to be clear
      13
          the only case that has foreign entities as a
          defense is Mr. Sills' Comanche County case.
      14
          And the stipulation that Mr. O'Connor is
      15
00:09
      16
          referring to, we think we've agreed to it.
      17
          And then after we had had those discussions,
      18
          the Comanche County case got filed and caused
      19
          folks at this table to say, "Wait a minute, we
          need to back up off of it and decide what we
      20
00:09
      21
          want to do." So I'm doubtful after that, if
          that's okay with your Honor. And again, not
      22
      23
          to lobby too much for the Third Amended
          Complaint, but I think when it's filed then
      24
      25
          all this stuff kind of goes away.
00:09
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1 THE COURT: I think that's 2 certainly possible. But I'll give you ten 3 days to come up with some, some agreement with regard to acceptance of service, and whatever 4 5 appropriate stipulations you need for 00:10 6 protection. 7 MR. SILL: And, your Honor, 8 sometimes in comparable cases we've reached an 9 agreement with defendants to dismiss one 10 defendant upon the agreement that that 00:10 11 defendant will indemnify the judgment, or good 12 judgment, so we will also discuss that with the defendant. 13 14 THE COURT: Very well. There was an indication that the plaintiff wanted to 15 00:10 16 directly file new actions in the Northern 17 District and without filing them in the 18 appropriate district and having been 19 transferred to the MDL. The defendant 20 objected to that. I'm not familiar with that 00:10 as being a normal procedure, and I don't --21 unless the defendant were to consent, it seems 22 23 like it raises venue problems that shouldn't be handled here. You still want to argue that? 24 25 Not really. Again, MR. KEGLOVITS: 00:11

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1
          that was one of the things we had worked out
       2
          when the Comanche County case got filed on --
       3
          different defendants served, and backed up off
       4
          of that. So I think your Honor doesn't prefer
       5
          that process. We had abdicated for it because
00:11
       6
          it avoids the cost of local counsel in the
       7
          jurisdictions --
       8
                     THE COURT: All right.
       9
                     MR. KEGLOVITS: -- and some
      10
          administrative things, but it's not
00:11
      11
          substantive.
      12
                     THE COURT: What happens when the
          cases go back though, if they go back?
      13
      14
                     MR. KEGLOVITS: Under the
          stipulation that was discussed between the two
      15
00:11
          of us, we would identify where the home
      16
      17
          district was, and then those cases would be
      18
          transferred back to that home district in the
      19
          direct filing.
      20
                     THE COURT: Well, I'll leave that
00:12
      21
          up to you. If you can reach an agreement,
          that's fine. I'm not going to require that.
      22
      23
                 On the point of plaintiffs' leadership,
          the request has been made that the Court
      24
      25
          appoint David Keglovits and Gable Gotwals as
00:12
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1
          lead counsel. And, Genentech had Matthew Sill
       2
          on here who --
       3
                     MR. BERGIN: Your Honor --
       4
                     THE COURT: -- does someone have a
       5
          preference here?
       6
                     MR. SILL: My partner, Matthew
       7
          Sill, wanted me to apologize for not being
       8
          here today. He is the governor from the
          Oklahoma Association of Justice to the
       9
      10
          National American Association of Justice, so
00:12
      11
          he's in Canada for the state meeting today and
      12
          couldn't be here. But, yes, and I have -- for
          Matthew's defense, I have Matthew's short form
      13
          bio, and he has served on steering committee
      14
          and executive committee on a number of
      15
00:13
      16
          multidistrict litigations, and it is he rather
      17
          than I we're asking you to appoint.
      18
                     Might I approach the bench with
      19
          this?
      20
                     THE COURT: You may.
00:13
      21
                                   Thank you. And I
                     MR. BERGIN:
      22
          believe that the defendants, to the best our
      23
          knowledge, have no objections to these
      24
          appointments. And we're also asking that Mr.
      25
          Keglovits and Mr. Sill be appointed as interim
00:13
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1
          class counsel, and the Court may want to
       2
          address that a little later.
       3
                      THE COURT: Mr. O'Connor?
                      MR. O'CONNOR:
                                     Your Honor, we do
       4
       5
          concur with the lead counsel and the co-lead
00:13
       6
          counsel that they are -- they have come
       7
          together on, but we think it's premature to
       8
          appoint an interim class counsel at this stage.
       9
                      We, for obvious reasons, think they
      10
          have a huge hurdle on certification and we
00:14
      11
          have some other issues that you're aware of on
      12
          the preemption. But in any event, that's the
      13
          only issue we had with the leadership
          structure was we thought it was premature to
      14
      15
          appoint interim class counsel at this point.
00:14
      16
                      THE COURT: All right, the Court
      17
          appoints Mr. Keglovits and Gable Gotwals as
      18
          lead counsel, and Matthew Sill with the Sill
      19
          Law Group as co-lead counsel.
      20
                     One of the matters I referred to as
00:14
      21
          coming over the transom was the plaintiffs'
          Motion for Leave to File a Third Amended
      22
      23
          Complaint.
      24
                     Mr. Keglovits, you want to address
      25
          that?
00:14
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1 MR. KEGLOVITS: Yes, your Honor. 2 It is our attempt to, as I earlier mentioned, 3 create a cooperative case governing document 4 that would bring together all claims of all of 5 the parties that we as counsel see as 00:15 6 appropriate in the first instance, and to 7 reduce the need for some of these other 8 administrative things. 9 Our hope is that working together 10 with Mr. Sills' group, we can jointly propose 00:15 11 a class definition of the motion to certify a class with jointly agreed upon claims. 12 13 spent a lot of time this morning working on a 14 proposal to come to you with today on a number of items and got some good cooperation. 15 00:15 16 our hope is that when we have this Third 17 Amended Complaint, if we get a chance to have 18 a Third Amended Complaint, it's really going 19 to streamline what's going to happen going forward in the case. It would include a 20 00:15 request to certify a national class, your 21 22 Honor. THE COURT: You intend this Third 23 24 Amended Complaint to govern the MDL? 25 MR. KEGLOVITS: That would be our 00:16

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1
          hope in consultation Mr. Sills' group, that
       2
          would be the operative document for all
       3
          parties claiming against Genentech.
                     THE COURT:
       4
                                  Okav.
       5
                     MR. KEGLOVITS: And in my
00:16
       6
          judgment -- and one more thing.
                                             It doesn't
       7
          really change the contour of the case as it
       8
          stands right now. There are a group of
       9
          practices that we represent, roughly a billion
      10
          dollars' worth of purchases of this drug.
                                                       Mr.
00:16
      11
          Sills' group is abdicating for a national
      12
          class already, and so it's really just going
      13
          to bring it all together in one place.
      14
                     THE COURT: And this pretty much
          assumes that Comanche County is one of them?
      15
00:16
      16
                     MR. KEGLOVITS: If we get together
      17
          and get the right class definition and the
      18
          right claims and the right defendants, it
      19
          would.
      20
                     THE COURT: Well, this Third
00:16
          Amended Complaint seems -- well, okay. What's
      21
          the defendant position?
      22
      23
                     MR. O'CONNOR: Your Honor, now --
      24
                     THE COURT: You can move that
      25
          microphone up just a bit, maybe we can turn it
00:17
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1
          up just --
       2
                     MS. TURNER: We'll do both.
       3
                     MR. O'CONNOR:
                                     We just saw -- we
       4
          had this underlying tone from the plaintiffs
       5
          throughout this of some supposed delay on our
00:17
       6
          end, and yet all of the work we did in
       7
          preparing the agenda and preparing a proposed
       8
          CMO, never was there any mention of yet
          another application to amend the Complaint.
       9
      10
          We see that on Monday and --
00:17
      11
                     THE COURT: We didn't have Comanche
      12
          County asking for a class action at that time
      13
          either.
      14
                     MR. O'CONNOR:
                                     That's correct.
          Well, we have in the last month, but
      15
00:17
      16
          regardless of that, we're now hearing about
      17
          another perhaps consolidated -- right now we
      18
          have two competing overlapping class actions.
      19
          We're hearing that there may be another but we
      20
          haven't seen it yet. It's a little hard to
00:17
          provide our position on it because I don't
      21
      22
          know what that Complaint's going to look like.
      23
          Right now they're very different class action
          allegations. One has California state law
      24
      25
          claims. One has a certain period of time
00:18
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1
          that's --
       2
                     THE COURT: All right, fine.
                                                    Maybe
       3
          I've misled you. I'm really interested in
       4
          whether or not you object to the filing of the
       5
          Third Amended Complaint.
00:18
       6
                     MR. O'CONNOR:
                                    Our, our --
       7
                     THE COURT: And I'm understanding
       8
          that there are allegations that would indicate
          they want a class action.
       9
      10
                     MR. O'CONNOR:
                                     Right.
                                             And if
00:18
      11
          we're -- you know, if the Third Amended
      12
          Complaint that we saw on Monday is the one
      13
          that would be the class action allegations, I
      14
          don't think we would have objection if this
          other Comanche class action complaint either
      15
00:18
      16
          goes away or is assumed into the one that was
      17
          filed Monday. But beyond that I just don't
      18
          know what's coming with this proposed
      19
          consolidation or resolution.
      20
                     THE COURT: Well, the elephant in
00:19
      21
          the room is obviously the class action aspect
          of this, which we haven't gotten to. But I
      22
      23
          don't have any problem with the Third Amended
          Complaint, and I'm going to allow the
      24
      25
          plaintiff leave to file that Third Amended
00:19
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Complaint. At least in the time frame that 1 2 we're in right now, that seems to be helpful 3 and not harmful, and it kind of gives us a better base to work with. That includes both 4 5 the Comanche County and the other pending 00:19 6 cases so... 7 Now, I understand you're alluding 8 to the fact that this could go a lot of different directions from here, and I 9 understand that. I think we're better served 10 00:19 by allowing that Third Amended Complaint. 11 12 Now, that brings us, according to 13 my notes, to the biggest timing issue, and I 14 think that the defendant wants to be able to file an early Motion For Summary Judgment on 15 00:20 the dispositive issue of Federal preemption. 16 17 The plaintiffs have objected to that and a 18 brief was filed, I guess this morning by the 19 defendant with regard to that. 20 And Mr. Keglovits, it seems like if 00:20 you can keep -- if I can keep this from 21 delaying things too long, that this is 22 23 something that needs to be decided fairly early or you could spend a lot of money 24 25 unnecessarily. 00:20

1 MR. KEGLOVITS: Two issues for us, 2 The first is we don't want to be your Honor. 3 cut by a thousand knifes. We've been coming to you saying by just denying the preemption 4 5 motion, now we've got the next best summary 00:21 6 judgment motion that's really going to make it 7 efficient for you to consider and show stay of 8 evidence. As your Honor knows, this case has been on file for a year and still hasn't 9 10 gotten to discovery, so we want to kind of 00:21 11 avoid that scenario. And we also, more 12 importantly, if your Honor allows the filing 13 of this summary judgment motion, which they 14 can file whenever they want to, our preference would be that it doesn't have impacts on the 15 00:21 16 other aspects of the case. Because the way 17 they're presenting it right now, they want to 18 file a motion and they want to stay everything 19 else. And as I understand their proposal, 20 they want to file a motion, present their 00:21 21 summary judgment evidence in a motion, and at that point we can ask to do discovery of the 22 23 information that's in their motion. We think that's way too restrictive. 24 25 If we're going to commence the 00:21

1 case, and I hope we will, and they have a 2 motion that they want to get on file in 30 or 3 60 or 90 days, I would like to use that period 4 of time to begin discovery on the issues that 5 are germane to the motion. So because, as 00:22 6 your Honor knows, sometimes people don't agree 7 on whether something is discoverable what --8 like Magistrate Wilson. There could be a lot of time wasted. And I hate for them to file a 9 10 motion and then the discovery starts, and we 00:22 11 have long delays until we can get the 12 discovery revolved and then a response. So in 13 short, we don't really have a position one way or the other on when they file this motion so 14 long as it's not at the first or the fourth. 15 00:22 16 But we want the other aspects of the case to 17 proceed as normal while they're considering 18 putting together this motion. 19 THE COURT: What type of discovery 20 do you feel is necessary to defend the motion? 00:22 21 I mean, you have a good idea of what is coming. 22 23 MR. KEGLOVITS: Well, we spent some time talking with counsel for the defense 24 25 about this proposal and asking questions about 00:22

1 what they needed to file. And at that point 2 it was last week, they didn't have a lot of 3 specifics about it. But, for example, one of 4 the questions we asked was: "Do you intend to 5 have expert affidavits in support of this 00:23 6 motion?" The answer was: "We haven't made 7 that decision." 8 We know that there are materials 9 that are provided to the FDA. We are wanting 10 to get those materials. We've been unable to 00:23 get them in unredacted form by way of a FOIA 11 12 request. They raised the issue in the submission that came in earlier this week, 13 14 Tuesday or Wednesday, and as I understand it that didn't get filed in the docket, at least 15 00:23 16 I haven't seen it on page streaming. But in 17 that submission they suggest that going 18 forward as we planned to would make it 19 impossible for them to create a manufacturing 20 facility that could comply with both the 00:23 21 Federal and the State law. Well, I think it would be fair for us to understand something 22 23 about their manufacturing processes to try to rebut that allegation. So those are some 24 25 examples of discovery that I think are going 00:24

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to be built into this Motion For Summary
       1
       2
          Judgment.
       3
                     THE COURT: Well, how much time do
          you think is necessary for discovery just for
       4
       5
          the preemption issue?
00:24
                     MR. KEGLOVITS: I hate to be one of
       6
       7
          those lawyers that doesn't give you a straight
          answer, but not having seen the motion yet, we
       8
          just kind of got a foreshadowing.
       9
                     THE COURT: Do you think you want
      10
00:24
          to wait until you see the motion before you --
      11
      12
          because you want 60 days before he files a
          motion?
      13
      14
                     MR. KEGLOVITS: I'd like to start
          on the things that I have identified as being
      15
00:24
      16
          information we think is going to be germane to
      17
          any motion. And then once we get the motion
      18
          we can supplement that with germane --
      19
                      THE COURT: Germane to any issue
          indicates discovery on the merits.
      20
00:24
      21
                     MR. KEGLOVITS: I'm sorry, what I
      22
          meant was germane to any issue that I see as
      23
          arising in the preemption contest. And that
      24
          their -- this case is going to present a lot
      25
          of discovery that has overlap between the
00:25
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1 merits and particular issues, class verification or issues of relevance. 2 3 hard to put any limits on it. We understand the efficiencies that 4 5 your Honor identified, and we certainly don't 00:25 6 want to go spending a whole bunch of money 7 collecting millions of gigabytes of ESI and 8 all kinds of topics if this case determines 9 motions, so we will be responsible in how we 10 approach it. We're just really hesitant to 00:25 11 have your Honor order limitations on us, not 12 knowing what we're going to get and knowing 13 how the case is processed to this point. 14 THE COURT: Mr. O'Connor? 15 MR. O'CONNOR: Your Honor, it 00:25 16 wasn't just a week ago that we had this 17 discussion. It was -- it was throughout the 18 process that we have been collaborating and 19 trying to confer with plaintiffs' counsel. 20 think this is a question of law for the Court 00:26 to decide. And as your Honor stated, we think 21 22 under the Manual for Complex Litigation and 23 for the statutes that created MDLs, that it certainly promotes efficiency and is 24 25 encouraged, particularly when it's potentially 00:26

1 a threshold dispositive issue. 2 We would have a motion, and it 3 would be supported by expert affidavit and 4 that would bring into consideration the 5 specific regulation, as well as the USP that's 00:26 6 at issue. There's been an assertion here that 7 we're not providing the quantity of product 8 that's on the label, and this Federal preemption regulation from the FDA, they all 9 10 have a specified parameter that we are 00:26 11 required to meet. Beyond that there's a 12 specification approved by the FDA that even 13 under their allegations of what has been 14 received by these institutions would be well 15 within those parameters. So we have a 00:27 16 situation where we're dealing with a biologic 17 that's actually grown; there's DNA enhancements. There's all kinds of -- this 18 19 isn't just a pill. It's a -- it's a 20 complicated, complex biologic that is then 00:27 freeze dried and delivered with a sterile 21 solution to be reconstituted. 22 23 All of this, as you might imagine, spent years before the FDA before approval. 24 25 And now they're asking that through state 00:27

```
1
          warrant, breach of warranty claims that that
       2
          ignore the entire regulatory framework that
       3
          exists; that it ignore all of the calibration
       4
          of manufacturing and everything else that's
       5
          been done and blessed by the FDA. So that's
00:28
       6
          why we believe it is a threshold issue.
       7
                      This is not a -- we don't believe
       8
          there's a lot of discovery that would be
       9
          required on the preemption issue because of
      10
          the regulations and the language of the
00:28
      11
          specifications as well. So we think it is --
      12
          we think it does support and promote
      13
          everything that the MDL in the name of complex
      14
          litigation asks us to do, as well as encourage
          the Court to do.
      15
00:28
                                 Well, if I agree that
      16
                      THE COURT:
      17
          this is the threshold issue and we need to
      18
          decide this first, what can you do to
      19
          expedite? I think you wanted 60 days from
      20
          today's date to file your Motion.
00:28
      21
                     MR. O'CONNOR:
                                     (Indicating).
      22
                     THE COURT: But it seems like you
      23
          should be giving a lot of this information to
      24
          the plaintiffs as soon as possible so that
      25
          we're not -- I don't like the idea of starting
00:29
```

the plaintiffs' discovery after you've filed 1 2 your motion in 60 days while they're just 3 sitting there doing nothing. If you have the information that you are going to rely on, it 4 5 seems like it would be better served if they 00:29 6 can start discovery rather quickly just as to 7 that issue. MR. O'CONNOR: And again, I don't 8 want to invite discovery disputes, but we 9 10 haven't seen much limitation on anything that 00:29 we've received so far. And so with the 11 12 regulation, the expert saying who's -- who is 13 in the industry and has FDA experience, with all of that, I just can't imagine. And I 14 sensed a little bit of that from what I just 15 00:30 16 heard, that there are elements of discovery 17 that would go well beyond this fairly simple regulatory framework that we've been 18 19 preempted as State law claims. 20 So I -- we would certainly be 00:30 21 willing, your Honor, to engage in and provide 22 whatever discovery you think is reasonable, 23 and if the experts relied on it, then we produce it, whatever that is. I don't 24 25 think that -- we're certainly not trying to 00:30

```
1
          hide anything with respect to the preemption
       2
          issue, but we've just never heard any
       3
          reasonable fashioning of discovery that would
          be aimed at the preemption issue. It's always
       4
       5
          been let's go get everything we can under the
00:30
       6
          sun, and meanwhile, you know, prevent us from
       7
          trying to go get key issues if they ever got
       8
          to a damages phase on their own
          reimbursements, where these institutions are
       9
      10
          reimbursed 106 percent of what they pay us, or
      11
          113 percent. Well, then, there's a wide range
      12
          of what they received, so they have a damage
      13
          hurdle too. And I'm getting beyond reaction,
      14
          but it's just that it's been difficult to
      15
          agree on what that discovery is, and so I've --
                     THE COURT: Well, I believe your
      16
      17
          option is full-blown discovery on preemption,
          on class, on merits, starting tomorrow. So it
      18
      19
          seems like even if you have disputes that come
      20
          up along the way that you're better off
00:31
      21
          getting your motion heard first in spite of
          some potential difficulties.
      22
      23
                     MR. O'CONNOR: I would agree there.
      24
                     THE COURT: All right.
                                              Mr.
      25
          Keglovits, anything else?
00:31
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MR. KEGLOVITS: Just two things, 1 2 First of all, I don't want you to your Honor. 3 leave here with the impression that we think 4 this is a particularly important motion. 5 There may have been a whole lot of research 00:32 6 done to create the secret sauce, but when you 7 pour it in a can and it says it's a 12 ounce can, it's not too hard to figure out if 8 there's 12 ounces in a can. And when you know 9 what the measurement is, it's not too hard to 10 00:32 11 write down what the measurement is. If you 12 choose to write down a number that's different 13 than what you put in, that's the problem. all this secret sauce and science aside, this 14 15 is a pretty simple case. 00:32 16 Having said that, I just heard now 17 for the first time that they're going to have 18 an expert, and I suppose for the first time 19 we'll get an exact date along with the Motion 20 For Summary Judgment, which is a little out of 00:32 21 phase with the way issues are typically presented to this Court. 22 I would think you 23 could get his affidavit well in advance of the filing of the motion so we can begin to 24 25 understand who we need to get to counter that 00:32

1 affidavit. And you --2 THE COURT: That's what I thought I 3 was at least proposing or throwing out is that the defendant needs to be forthcoming with all 4 5 of the information that they have already that 00:33 6 they are going to use in formulating their 7 Motion For Summary Judgment, and you can start discovery on that right away. 8 9 MR. KEGLOVITS: (Indicating). Then after the motion 10 THE COURT: 00:33 11 is filed, I assume you'll want some clean up 12 time. But, you know, I think this is an issue 13 that I don't know whether it's that critical 14 or not; I have no idea at this time. But I think if it's one that can dispose of the 15 00:33 16 entire case then we need to go ahead and do 17 that first. But I don't want to -- I don't 18 want to end up being six months down the road 19 just doing discovery on this motion and your responses and so forth. So it seems like to 20 00:33 21 me that if the defendant can start giving you affidavits, information, whatever they already 22 23 have possession -- in their possession, and what they obtain as they go and you can start 24 25 discovery on that, well then you wouldn't need 00:34

1 more than maybe 30 days after the motion's 2 filed. 3 MR. KEGLOVITS: Yes, it all depends on the timing. And it would be helpful today 4 5 if they told us who their expert is or what 00:34 6 her or his qualifications are so we can begin 7 our search for the right person to address that. 8 9 THE COURT: All right. I'm not 10 going to -- I'm going to stay the discovery on 00:34 11 the class certification matter and the merits 12 of the case at this time. I'm going to allow 13 the defendant to file 30 days from today's 14 date, unless that falls on a Saturday or a Sunday, the Motion For Summary Judgment based 15 00:35 16 on the preemption. I'm going to require the 17 defendant to provide the name of any and all 18 experts that you're aware of by tomorrow, and 19 any additional experts that you contemplate 20 using, well, within 30 days of today's date. 00:35 21 And I want you to begin the process and begin the process, I mean, like within the next ten 22 23 days of providing the plaintiffs with the material that you are already have. 24 25 (Off the Record) 00:36

1 I'm -- that apparently THE COURT: 2 wasn't what I understood. Sixty days to file 3 a motion. What I want to happen within 30 days is the names of all potential experts, 4 5 whatever experts you're aware of right now I 00:36 6 want you to give them tomorrow. 7 But what concerns me is that as 8 this progresses there may be some changes in personnel, and what I want to make sure of is 9 that at some point before this 60 days is up 10 00:36 that everybody knows who's -- who the players 11 12 And 30 days may be too long, I mean, we are. 13 can discuss that. But I want, you know, I 14 want this to be ongoing. And I want the discovery to be on issues that bear on or 15 00:37 16 reasonably might bear on the question of the 17 Federal preemption, and that should be taken 18 in a broader sense. 19 I don't agree with the defendant 20 that it's going to be that narrow. It can be 00:37 21 just wherever your discovery takes you. When 22 you get -- it gets to the point that it's more 23 on class or on the merits of the case, then all you have to do is call, call me or call 24 25 the Magistrate and we'll let you know. 00:37

```
Now, Mr. Keglovits, what problems
       1
       2
          do you see that I've just created?
       3
                     MR. KEGLOVITS: Well, I want to
          talk with some of the people who are smarter
       4
       5
          than me before I identify them.
00:38
       6
                      The thing that's out there that I
       7
          didn't hear in your order was when our
       8
          response would come following the filing of
          their motion.
       9
      10
                      THE COURT: Thirty days is what I
00:38
      11
          intended.
      12
                     MR. KEGLOVITS: All right. Could
      13
          we have leave at least to come back to you, if
          we think it's going to take more than that,
      14
          because we're having trouble finding an expert
      15
00:38
      16
          or something like that?
      17
                     THE COURT: You may, but I assume
      18
          you're going to -- I assume you already have
      19
          some ideas about experts that are out there.
      20
          But sure, thirty days is what I anticipate it
00:38
      21
          will take you to respond, if you get all the
      22
          information that I'm hoping that they're going
      23
          to give you. And they're going to be
      24
          forthcoming, and you're going to have this
      25
          ahead of time. And if the games start and,
00:38
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```
1
          you know, switching experts and switching
       2
          ideas and reports and stuff then yes, I'll
       3
          give you more time.
                     MR. KEGLOVITS: And then could I
       4
       5
          maybe ask your Honor to expedite response time
00:39
       6
          on Interrogatories, Request for Admission,
       7
          Request for Production to make it 15 days
       8
          instead of 30, allowing for the compressed
          schedule?
       9
      10
                     THE COURT: I think that's
00:39
      11
          appropriate. What other? Fifteen days
      12
          response time on the Interrogatories?
      13
                     MR. KEGLOVITS:
                                     Written discovery,
          and I don't know whether we're going to need
      14
          any depositions of their people, but I'm
      15
00:39
      16
          assuming within this discovery you've outlined
      17
          we identify someone we need to depose, we've
      18
          got the leeway to do that.
      19
                      THE COURT:
                                  In the case of
      20
          Genentech it wasn't a case, it was an order,
00:40
      21
          the initial case management scheduling order.
          They took care of a lot of those things
      22
      23
          that -- would that be preferable, the Court go
          ahead and order today and give you time frames
      24
      25
          for depositions and spacing depositions be
00:40
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```
1
          completed, Interrogatories?
       2
                     MR. KEGLOVITS: I think that would
       3
          help.
       4
                     THE COURT:
                                 All right. We'll do
       5
          that.
                 So that's going to put you on a pretty
00:40
       6
          short fuse on this. Is everyone prepared to
       7
          march forward just on the preemption?
       8
                     MS. DONAHUE: Good morning, your
                  I'm Alicia Donahue, I'm the --
       9
          Honor.
      10
                     THE COURT: Do you need more time
00:40
      11
          for you to be able to recover from...
      12
                     MS. DONAHUE: Yes.
                                          I'm here
      13
          compromised. One issue that is outstanding
      14
          that will affect the discovery situation is
          that Protective Order. Prior to going to the
      15
00:41
      16
          GP&L panel and coming back to you, we had a
      17
          Protective Order motion with Magistrate Lane.
      18
          He entered an Order. There's one provision of
      19
          the Protective Order that he entered that we
          at Genentech have issue with. We filed an
      20
00:41
          objection with your Honor and briefed that,
      21
      22
          but then new things -- everything started
      23
          happening, so that is an issue that's been
      24
          standing, and it's very important to Genentech
      25
          in terms of their highly confidential information
00:41
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```
1
          that much of this discovery; in fact, all of
       2
          this discovery will be put on the table.
       3
                     You know, most of our manufacturing
          documents are formulas, are very highly
       4
       5
          confidential. They are filed with the FDA,
00:41
       6
          so, you know, the list is fairly long.
       7
          we'll --
       8
                      THE COURT: Do you anticipate
          reaching these issues in this type of
       9
      10
          discovery just on preemption?
00:42
      11
                     MS. DONOHUE: I think a lot of it
      12
          will, you know, will come into play, but
      13
          assuming that discovery is what the
      14
          plaintiff's made it sound like. I could
          propose, the only issue that we have on the
      15
00:42
      16
          order is that we have asked for an attorneys'
      17
          eyes only provision for highly confidential
      18
          documents.
      19
                      The order that the Magistrate
      20
          entered allows for two designees from each
00:42
      21
          corporate defendant -- I'm sorry, or corporate
          plaintiff to also review the information.
      22
      23
          Given that we are now in a class action
          situation and there's multiple plaintiffs,
      24
      25
          it's -- Genentech having a right, since it was
00:42
```

```
1
          put out there. So what I would propose, your
       2
          Honor, is that unless we have the attorneys'
       3
          eyes only provision, and their expert of
          course who will need to see it, you know, that
       4
       5
          it's kept highly confidential for attorneys
00:43
       6
          and experts to review and not further than
       7
          that at this -- at this stage.
                     THE COURT: Only for the discovery
       8
       9
          that's taking place with regards to --
      10
                     MS. DONAHUE:
                                   Uh-huh.
00:43
                     THE COURT: -- the preemption?
      11
                     MS. DONAHUE: That would be fine
      12
                  If need be, and we feel we needed to
      13
          then.
          further it, should the provision not take care
      14
          of the case, we will be back if need be.
      15
00:43
      16
          you know, hopefully not. Because I do think a
      17
          lot of -- a lot of the information we're
      18
          concerned about will be coming out in this
      19
          phase given the discovery plan that we've --
      20
          that has been put in place.
00:43
      21
                     THE COURT: Mr. Keglovits?
      22
                     MR. KEGLOVITS:
                                      The way it was
      23
          played out in front of Magistrate Judge Wilson
          was we are concerned that if we're not allowed
      24
          to share information with our clients, and
      25
00:43
```

1 most of the officers are clients; most of the 2 directors of our clients are practicing 3 oncologists. We benefit greatly from their help in understanding the information we get. 4 5 So we want to be able to go to them with what 00:44 6 we receive from Genentech and get their views 7 about it. 8 I don't see a real issue here if we identify only two representatives of each 9 client that we can share this information 10 00:44 with, and we're not talking about punitive 11 12 class members. 13 THE COURT: Well, if you have two of each client, you're up to about 30? 14 15 MR. KEGLOVITS: That's right. 00:44 16 remember, we're not competitors of Genentech. 17 We're not trying to manufacture these drugs. 18 All we want to do is present whatever 19 scientific information comes to people who are 20 very skilled in this science. And to do 00:44 21 otherwise bars us to go hire a bunch of people 22 to do what our physicians probably could do 23 without hiring anyone. To say nothing of, ordinarily, unless you've got a competitor 24 25 versus competitor, there aren't restrictions 00:44

```
1
          on talking with your clients about the
       2
          strengths and weaknesses of the case.
       3
          just don't see that this issue is properly
          placed in this case.
       4
       5
                     Now remember, this is a patent
00:45
          communication, so many of these disclosures
       6
       7
          have been made so that they can get this
          monopoly position. I think it's all presented
       8
       9
          in briefs to your Honor that come out of the
      10
          appeal.
00:45
      11
                      Our preference would be that your
      12
          Honor sustain the decision from Magistrate
      13
          Judge Wilson, and that Protective Order apply
      14
          to this discovery as well as all the rest of
      15
          it.
00:45
      16
                      THE COURT: My understanding
      17
          originally was they were worried about
      18
          competitive information and pricing information,
      19
          and I'm just not sure why we're getting into
      20
          much of that on preemptions.
00:45
      21
                      MS. DONAHUE: May I approach, your
      22
          Honor?
      23
                      THE COURT: You may.
      24
                      MS. DONAHUE:
                                    There were --
      25
          originally, when we were dealing with one of
00:45
```

1 the preemption issues, there were two levels 2 of confidential information that we were 3 concerned about. One being on regulatory, you know, manufacturing information, and then the 4 5 other being commercial as you said. 00:46 Now, we're concerned, you know, 6 7 because of where we are with the bench motion, 8 we're concerned solely about the regulatory information for this phase. And I wanted to 9 add that if the plaintiffs were to go to the 10 00:46 FDA and request, for instance, our 11 12 biologically -- or biological licensing 13 application, it would come back to them highly redacted because of the trade secret 14 information that's contained there. And we 15 00:46 cited cases in our brief, but I think also 16 17 it's just -- it's a great, you know, fear for 18 Genentech that even, you know, the two people 19 that may be designated from each of these entities, even though they're not competitors, 20 00:46 per se, and they're not seen as doing business 21 22 with them, once the information's out there, 23 it's a very slippery slope. And given the level of highly, highly, highly confidential 24 25 trade secret information that we're talking 00:46

```
1
          about, I cannot overstate the importance of
          this issue from Genentech's, you know,
       2
       3
          competitive and trade secret point of view.
          It's just -- it's so important to them, so...
       4
       5
          and I don't think that we're asking for too
00:47
       6
          much; the attorneys' eyes only and the expert
       7
          person matter because it will be covered under
          the confidentiality agreement. And if others
       8
          need to see it, we can address that on a
       9
      10
          case-by-case basis.
00:47
      11
                     But given the number of plaintiffs
      12
          we've got and the type of information we're
      13
          talking about at this point, we would
          respectfully request our point of view.
      14
      15
          you.
00:48
      16
                      THE COURT:
                                  All right. I'm going
      17
          to sustain Magistrate Wilson's position and
      18
          order on the Protective Order with the
      19
          exception that, you know, we'll entertain on a
      20
          case-by-case basis the specific matters that
00:48
      21
          relate to trade secrets and pricing.
      22
                      Is there anything else that's
      23
          beyond those two things that are -- seem to be
      24
          creating this spurn? Okay.
      25
                     Electronically stored information,
00:49
```

1 apparently you were attempting to come to an 2 agreement on that, and it's broken down or has 3 it been addressed of late? Is there any reason you can't have the PSI protocol 4 5 finalized by the time the Motion For Summary 00:49 6 Judgment is ripe? 7 MR. KEGLOVITS: I wouldn't think 8 so, your Honor, but the hang up has been how 9 many custodians it serves. Genentech has 10 proposed that we agree to some fixed number, 00:49 11 but we have said is we don't really know 12 enough about an inspection process to know how many people served in a particular role over a 13 14 number of years, how many roles there are. think our preference would be to have them 15 00:50 16 explain to us how the manufacturing process 17 works and whose got what titles; how the 18 marketing process works and whose got what 19 titles, and then identify for them which of 20 those titles we want you to search ESI for 00:50 21 over those. 22 As I understand it the way we came 23 to kind of a bump in the road, and then the subsequent filings kind of took us off of the 24 25 ESI track because of the trip to the MDL. 00:50

```
1
                     MR. O'CONNOR: To answer your
       2
          question, I think we could reach an agreement
       3
          by the time the Summary Judgment is ripe.
                     THE COURT:
                                  Thank you. And if
       4
       5
          there are problems, of course, we'll handle
00:50
       6
          those as they come up. It seems like they'd
       7
          like for you to have future status conference
       8
          dates in place. I'm not sure we're ready for
       9
          that. You know, I think we might have a
      10
          shorter discussion just with lead counsel and
00:51
      11
          co-lead counsel and the defendant's counsel
      12
          maybe in September to see where we are, and
      13
          we'll try to find a date that works for
          everybody. But I don't -- I don't think we're
      14
      15
          going to need a full-blown status conference
00:51
      16
          at that time. All right. What could we have
      17
          that I've not addressed or we have not
      18
          addressed?
      19
                     MR. KEGLOVITS:
                                     From the
      20
          plaintiffs' respective, we're good.
00:51
      21
                     MR. O'CONNOR: Agreed, your Honor.
      22
                     THE COURT: Okay. It's been nice
      23
          seeing you all. We won't I'm going to go
      24
          Santa Barbara for July so I won't see you
      25
          then. Let's see, all right, or you might
00:52
```

```
1
           indicate to Ashley your schedules in September
       2
          and compared with mine and see if there's a
       3
          time where we can just have a little get
       4
           together and not as formal as this and just
       5
          kind of see where we are and then map out some
00:52
       6
           future conferences from that point forward.
       7
                      MR. KEGLOVITS:
                                       The joint panel on
       8
          multidistrict litigations was kind enough to
       9
           invite us to Santa Barbara to have argument on
      10
           the question of consolidation -- and I think I
00:52
      11
          will speak for Alicia, but we found it a very
      12
          helpful place to have arguments, so if your
      13
          Honor's inclined, maybe that would be good or
      14
          maybe not.
      15
                      (Off the Record)
00:53
      16
                      THE COURT:
                                  All right.
                                               Thank you
      17
          all.
                         (RECORD CONDLUDED)
      18
      19
      20
      21
      2.2
      23
      24
      25
```

```
1
                      CERTIFICATE
2
    STATE OF OKLAHOMA
                           ss.
3
    COUNTY OF TULSA
 4
5
       I, Elizabeth Ann Behles, a Certified
6
    Shorthand Reporter in and for the State of
7
    Oklahoma, do hereby certify that the above
    Transcript of Hearing was taken by me on the
8
9
    23rd day of June 2016 and thereafter transcribed.
           IN WITNESS WHEREOF, I have hereunto
10
11
    set my hand this 28th day of June, 2016.
12
13
               s/Elizabeth Ann Behles, CSR #121
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